

in which the newly-presented claims are believed to patentably distinguish over them, a brief description of the present invention and its advantages may be helpful.

As discussed in the background of the present application, identification of biological samples is of critical importance in hospitals, testing laboratories and other institutions. One problem with existing identification schemes is that they are not universal, but rather are specific to the institution or organization which developed them. Thus, when a given sample crosses institutional or organizational boundaries (e.g., when it is sent from a hospital or doctor's office to a testing laboratory, or vice-versa), the identification scheme is no longer useful. The second institution must then employ a different identification scheme which may be incompatible with the first one. The necessity of adopting and using multiple identification schemes is not only cumbersome, but introduces the possibility of error in identifying biological samples during the various processing, handling and reporting steps that must typically be carried out.

The present invention adopts an entirely new sample identification model which avoids the disadvantages and limitations of the prior art. Rather than focusing at the outset on identifying a particular *sample*, the present invention focuses on identifying the *container* in which the sample is or will be placed. Typically, although not necessarily, the identifying marking is placed on the container during the initial manufacturing process, long before the container is associated with a particular biological sample.

Container markings of various kinds have, of course, been widely used in the prior art. What primarily distinguishes the present invention, however, is the fact that the identifying marking is *universally unique*. The term *unique* is used in the conventional sense to indicate that

no two containers will have the same identifying marking. This may be true in either an absolute or a relative sense. For example, if the field of interest is biological testing, it is sufficient if all containers which are sold for use in biological testing have different identifiers. It would not matter if containers sold for other purposes share some or all of the same identifiers, because such containers would not be purchased or used by those in the biological testing field.

The term *universal* indicates that the uniqueness of the identifier is preserved across institutional or organizational boundaries. In other words, a container manufactured by one company must not have the same identifier as a container manufactured by another company. This assures that the ultimate purchaser or user will always obtain containers with unique identifiers, even in situations where the containers are obtained from multiple sources. Again, however, universality may be maintained in a relative rather than in an absolute sense. For example, if all purchasers restrict their purchase of biological testing containers to domestic sources, or to sources that are members of an association or that have the approval of a certifying body, it will suffice if the uniqueness of the container identifiers is universal only among those sources. It will not matter if the uniqueness of the container identifiers is not maintained with respect to other sources.

Once the purchaser or user is assured of having a container with a universally unique identifier, the process of properly identifying biological samples becomes much easier and more reliable. When the container is ready to be used, the unique identifier is associated with information relating to the biological sample that is or will be placed in the container. The information may comprise patient identity, tests ordered, process history, and so on. The

association between the identifier and the sample information may take place in a computer database, in a handwritten record, or otherwise. The sample can thereafter be tracked using the container identifier alone, without any chance of misidentification, even when the sample travels between different institutions and organizations. At any time during processing or handling of the sample, the unique container identifier can be used to access the associated sample information. Thus, not only does the unique identifier avoid the possibility of sample misidentification, but it also maintains confidentiality since the unique identifier is the only marking that may appear on the container itself.

Newly-presented independent method claims 33 and 43 both require the use of a "universally unique" container identifier and the step of "associating" the container identifier with other information. The other information is described in claim 33 as "information relating to [a] biological sample", and in claim 43 as "information pertaining to use, planned use or contents of [the] container". As demonstrated below, these limitations are not met by any of the references which have been cited by the Examiner, nor are they obvious in view of the cited references.

U.S. Patent No. 5,683,786 (Kavanaugh), although not relied upon in the latest Office Action, was cited against originally-filed claims 1-16 in the Office Action mailed on January 27, 2000. The Kavanaugh '786 patent discloses a microscope slide that has been provided with a laser-etched bar code marking. Importantly, however, there is nothing in the '786 patent to indicate that the bar code marking is *universally unique* in the sense intended by the present invention. On the contrary, the specification of the '786 patent states that "the bar code may be

used to identify the microscope slide 30 with critical information about the sample contained on the microscope slide 30" (column 3, lines 40-42). In other words, the bar coding used in the '786 patent is simply a machine-readable version of the kind of information that might previously have been applied to the slide by hand at the point of use -- that is, information about the *sample* rather than information about the *slide*. This is consistent with the fact that the inputs to the laser-etching device shown in Fig. 4 of the '786 patent are provided by a human operator. The specification states that "the operator keys in identifying characters *in the same form as if such characters were hand-written on the marking surface coating 14 of the microscope slide 10*" (column 5, lines 62-65; emphasis added). The purpose of the bar codes in the Kavanaugh '786 patent is to provide the slide with an indelible marking that can be used to verify hand-written information about the sample, rather than to provide a unique identifier for the microscope slide itself (see, column 6, lines 20-36).

U.S. Patent No. 4,985,115 (De Rossett, Jr.) was cited as a secondary reference in the Office Action mailed on January 27, 2000. The '115 patent appears to be relevant only for its disclosure of etching bar codes onto glass. It does not teach or suggest the use of universally unique identifiers for containers. Accordingly, this reference is not believed to be relevant to the present invention as defined in new independent claims 33 and 43.

U.S. Patent No. 5,397,410 (Handly) was cited in the January 27, 2000, Office Action for its disclosure of incorporating a ceramic film coating with a bar code pattern onto glassware.

U.S. Patent No. 5,801,356 (Richman) was cited in the same Office Action for its disclosure of using abrasion as an alternative to laser-etching in forming letters on glass. Again, these

references are not seen as being relevant to the present invention as defined in new independent claims 33 and 43. The Applicant also notes that the Richman '356 patent is a reference only under 35 U.S.C. § 102(e), and hence no admission is made that this reference constitutes prior art with respect to the present invention.

U.S. Patent No. 4,842,153 (Hulon) was initially applied against the Applicants' claims in the final Office Action mailed on October 25, 2000, and is also relied upon in the current Office Action. The Hulon '153 patent discloses a shipping tube 10 which encloses a test tube 60 containing a biological product. The upper tubular section 14 of the shipping tube 10 has identification information integrally imprinted on its exterior surface. However, the specification of the Hulon '153 patent describes the identification information as follows:

The identification information is available for identifying the brand of the shipping tube, the indication that it contains hazardous biological material, and a warning not to reuse the shipping tube. Other information could also be printed, labeled or otherwise placed in area 32.


There is no suggestion in this statement that the identification information printed on the shipping tube 10 of the Hulon '153 patent is, or could be, a *universally unique* container identifier as in Applicants' independent claims 33 and 43. Without such universal uniqueness, the identification information discussed in the '153 patent cannot be used to achieve the objectives of the present invention.

U.S. Patent No. 5,609,778 (Pulaski et al.) was cited as a secondary reference in the Office Action mailed on June 5, 2001. The Pulaski et al. '778 patent discloses laser marking of glass and plastic surfaces, for identification purposes and the like. Bar codes are also mentioned

(column 4, lines 60-63). However, there is nothing in the '778 patent that suggests the use of a *universally unique* container identifier for the purposes disclosed in the present application.

In view of the foregoing arguments and claim amendments, withdrawal of the outstanding rejections and allowance of new claims 33-50 is respectfully requested. Should the Examiner wish to discuss any aspect of this application with the Applicants' representative, the Examiner is invited to contact the undersigned attorney at the local telephone listed below.

Respectfully submitted,



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**Marked-Up Version to Show Changes Made**

In one embodiment of the invention, the marking 24 defines a surface or area having a specular reflectance that is greater than that of the container 20 adjacent to the marking 24. In this embodiment, the amount of light that is directly reflected from the marking 24 is [less] greater than that reflected by the surface of the container 20 adjacent to the marking 24.

In certain of the above-described embodiments, several individual markings 24 cooperate together to provide a unique identifying function. In other embodiments, a single marking 24 or a small number of markings may be [conFigured] configured to provide unique identifying pieces of information. For example, a single marking 24 may comprise an area on a container 20 having a detectably unique shape that functions as an identifier. In addition, the marking 24 may comprise a number of different markings 24 interconnected so as to create a single marked area 24.

Figures 5(a) and 5(b) illustrate examples of an output signal obtained from a light emitter-detector pair in one embodiment when utilized to detect spaced markings 24 on a container 20. The output signal indicates the amount of reflected light detected versus time. Figure 5(a) illustrates an example output [sinal] signal obtained when the markings 24 constitute laser etched areas of the outer surface of the container. Figure 5(b) illustrates an example output signal obtained when the markings 24 comprise areas of translucent adhesive tape applied to the outer surface 22 of the container 20. In both instances, the markings 24 are clearly identifiable as peaks in the output signal, while the unmarked areas comprise "valleys" or dips in the output signal.

